Voluntary Medical Device Recall
SAK- 302 Dialysate Concentrate

May 16, 2014

Dear NxStage Distributor

Description of Problem

NxStage Medical, Inc. has confirmed through internal testing that specific lots of SAK Dialysate Concentrate contain aluminum levels which exceed internal product specification. NxStage Medical, Inc. was made aware of the issue through customer complaints indicating an increase in the serum aluminum levels of patients over a one year period identified during routine, annual blood tests. There have been no adverse health consequences or medical interventions reported.

The NxStage SAK concentrate, a component of the NxStage Pureflow SL module, is intended to contain the essential electrolytes, buffer, and glucose in the appropriate concentrations that when proportioned with purified water produces dialysate. The NxStage Pureflow SL module is an optional accessory to the NxStage System One™ that prepares dialysate for use during hemodialysis, as prescribed by the physician.

The affected product and lot can be found in Attachment A.

The affected lot was manufactured in December 2013

Potential Risk

NxStage Medical, Inc. initiated an extensive investigation and confirmed that specific lots of sodium lactate, a raw material used in the production of the SAK dialysate concentrate, contained levels of aluminum which would exceed specification when the concentrate was fully diluted.

There have been no adverse health consequences or medical interventions reported. Specifically increases in patient serum aluminum levels averaging 10µg/L have been reported within specific dialysis networks. The aluminum levels of the affected lots range from 11.5 µg/L to 13 µg/L when the concentrate is fully diluted. The product specification requires concentrate aluminum levels to be less than 10 µg/L. NxStage believes that the likelihood of any serious adverse health consequences is remote at the serum aluminum levels currently reported. NxStage has confirmed that other SAK lots in distribution meet the specification for aluminum levels.

Action to be taken by Distributors

1. Notify any hospitals, centers, renal units, and patients to whom you shipped SAKs (A template letter has been included in this package to help you explain this to customers).
2. Customers should check all boxes and individual bags. If they find any of the affected lot in Attachment A, they should separate them from their other SAKs and not use them.
3. Arrange for affected lots to be returned to you
4. Check all boxes in your SAK inventory. If you find any boxes of the affected lot in Attachment A separate them from your other SAKs and do not use them.
5. Check all individual SAKs in all inventory locations. If you find any bags of the affected lot in Attachment A separate them from your other SAKs and do not use them.
6. Quarantine affected lot.
7. Complete inventory reconciliation form and provide the completed form to NxStage.
8. NxStage will provide disposition instructions for all quarantined lot.
9. NxStage's authorized representative will be in contact with you to define the strategy for notifying the Competent Authorities.

Please know that we are committed to continuous improvement in order to provide you with the best products available and apologize for any inconvenience that this issue may have caused.

If you have any questions or comments, please feel free to contact Dean Chan at + 001 1 978-332-8359 or dchan@nxstage.com.

Regards,

Todd M. Snell
Senior Vice President
Quality Assurance, Regulatory, Clinical Affairs

Attachment A- Affected SAK Lot

SAK-302

Manufacturing Date	SAK-302 Lot Number
Dec-2013	31279118

Voluntary Medical Device Recall

SAK Dialysate Concentrate

SAK-301, SAK-302, SAK-303, SAK-304, SAK-305, SAK-306, SAK-307

May 16, 2014

Dear NxStage Customer:

Description of Problem

NxStage Medical, Inc. has confirmed through internal testing that specific lots of SAK Dialysate Concentrate contain aluminum levels which exceed internal product specification. NxStage Medical, Inc. was made aware of the issue through customer complaints indicating an increase in the serum aluminum levels of patients over a one year period identified during routine, annual blood tests. There have been no adverse health consequences or medical interventions reported.

The NxStage SAK concentrate, a component of the NxStage Pureflow SL module, is intended to contain the essential electrolytes, buffer, and glucose in the appropriate concentrations that when proportioned with purified water produces dialysate. The NxStage Pureflow SL module is an optional accessory to the NxStage System One™ that prepares dialysate for use during hemodialysis, as prescribed by the physician.

The affected products and lots can be found in Attachment A.

The affected lots were manufactured between April 2013 and February 2014.

Potential Risk

NxStage Medical, Inc. initiated an extensive investigation and confirmed that specific lots of sodium lactate, a raw material used in the production of the SAK dialysate concentrate, contained levels of aluminum which would exceed specification when the concentrate was fully diluted.

There have been no adverse health consequences or medical interventions reported. Specifically increases in patient serum aluminum levels averaging 10µg/L have been reported within specific dialysis networks. The aluminum levels of the affected lots range from 11.5 µg/L to 13 µg/L when the concentrate is fully diluted. The product specification requires concentrate aluminum levels to be less than 10 µg/L. NxStage believes that the likelihood of any serious adverse health consequences is remote at the serum aluminum levels currently reported. NxStage has confirmed that other SAK lots in distribution meet the specification for aluminum levels.

Action to be taken by Customers

1. Check all boxes in your SAK inventory. If you find any boxes of the affected lots in Attachment A separate them from your other SAKs and do not use them.

2. Check all individual SAKs in all inventory locations. If you find any bags of the affected lots in Attachment A separate them from your other SAKs and do not use them.

3. Complete the attached Recall Reply Form and fax to NxStage UK Customer Care (0845 437 9544).

4. Contact NxStage UK Customer Care to arrange for return of all affected product and for replacement product to be sent.

Please know that we are committed to continuous improvement in order to provide you with the best products available and apologize for any inconvenience that this issue may have caused.

If you have any questions or comments, please feel free to contact NxStage UK Customer Care at 0800 048 8352.

Regards,

T M. Snell
Senior Vice President
Quality Assurance, Regulatory, Clinical Affairs

Attachment A- Affected SAK Lots

SAK-301

Manufacturing Date	SAK-301 Lot Number
Jan-2014	40179162
Dec-2013	31279127

SAK-302

Manufacturing Date	SAK-302 Lot Number
Dec-2013	31279118
Apr-2013	3047923
Jan-2014	40179127

SAK-303

Manufacturing Date	SAK-303 Lot Number
Jun-2013	3067902

SAK-304

Manufacturing Date	SAK-304 Lot Number
Jan-2014	40179029
Dec-2013	31279094
May-2013	3057908
Jan-2014	40179019

SAK-305

Manufacturing Date	SAK-305 Lot Number
Jan-2014	40179026
May-2013	3057901

SAK-306

Manufacturing Date	SAK-306 Lot Number
Apr-2013	3047917

SAK-307

Manufacturing Date	SAK-307 Lot Number
Jan-2014	40179036

Voluntary Medical Device Recall
SAK Dialysate Concentrate
SAK-302, SAK-304, SAK-305

May 16, 2014

Dear NxStage Distributor

Description of Problem

NxStage Medical, Inc. has confirmed through internal testing that specific lots of SAK Dialysate Concentrate contain aluminum levels which exceed internal product specification. NxStage Medical, Inc. was made aware of the issue through customer complaints indicating an increase in the serum aluminum levels of patients over a one year period identified during routine, annual blood tests. There have been no adverse health consequences or medical interventions reported.

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The affected products and lots can be found in Attachment A.

The affected lots were manufactured between April 2013 and February 2014.

Potential Risk

NxStage Medical, Inc. initiated an extensive investigation and confirmed that specific lots of sodium lactate, a raw material used in the production of the SAK dialysate concentrate, contained levels of aluminum which would exceed specification when the concentrate was fully diluted.

There have been no adverse health consequences or medical interventions reported. Specifically increases in patient serum aluminum levels averaging 10µg/L have been reported within specific dialysis networks. The aluminum levels of the affected lots range from 11.5 µg/L to 13 µg/L when the concentrate is fully diluted. The product specification requires concentrate aluminum levels to be less than 10 µg/L. NxStage believes that the likelihood of any serious adverse health consequences is remote at the serum aluminum levels currently reported. NxStage has confirmed that other SAK lots in distribution meet the specification for aluminum levels.

Action to be taken by Distributors

1. Notify any hospitals, centers, renal units, and patients to whom you shipped SAKs (A template letter has been included in this package to help you explain this to customers).

2. Customers should check all boxes and individual bags. If they find any of the affected lots in Attachment A, they should separate them from their other SAKs and not use them.

3. Arrange for affected lots to be returned to you

4. Check all boxes in your SAK inventory. If you find any boxes of the affected lots in Attachment A separate them from your other SAKs and do not use them.

5. Check all individual SAKs in all inventory locations. If you find any bags of the affected lots in Attachment A separate them from your other SAKs and do not use them.

6. Quarantine affected lots

7. Complete inventory reconciliation form and provide the completed form to NxStage

8. NxStage will provide disposition instructions for all quarantined lots

9. NxStage's authorized representative will be in contact with you to define the strategy for notifying the Competent Authorities.

Please know that we are committed to continuous improvement in order to provide you with the best products available and apologize for any inconvenience that this issue may have caused.

If you have any questions or comments, please feel free to contact Dean Chan at + 001 1 978-332-8359 or dchan@nxstage.com.

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Todd M. Snell
Senior Vice President
Quality Assurance, Regulatory, Clinical Affairs

Attachment A- Affected SAK Lots

SAK-302

Manufacturing Date	SAK-302 Lot Number
Jan-2014	40179105
Dec-2013	31279118
May-2013	3057915
Apr-2013	3047924

SAK-304

Manufacturing Date	SAK-304 Lot Number
Jan-2014	40179029
May-2013	3057919

SAK-305

Manufacturing Date	SAK-305 Lot Number
Jan-2014	40179026